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Yoshiharu Sato

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EXAMINER

RAMDHANIE, BOBBY

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,588	Applicant(s) SATO, YOSHIHARU	
	Examiner BOBBY RAMDHANIE	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/04/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 17, & 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Simons et al (US6036924). Regarding Claim 1, Simons et al teaches an analytical tool cartridge comprising: a case including a storage space (Figure 4B Item 150) and a retrieval port that communicates the storage space with an external space (Figure 4B Item 156); and a plurality of analytical tools stored in the storage space in a stacked state (Figure 4B Item 159); the analytical tool cartridge further comprising a retrieval mechanism for retrieving the analytical tools one at a time from the case via the retrieval port (Figure 4B Item 160 A/B).

3. For Claim 17, Simons et al teaches a set of an analytical tool cartridge and an analyzer (Simons et al; Figure 5A; Items 166 & 150), the analytical tool cartridge comprising: a case including a storage space and a retrieval port that communicates the storage space with an external space (Simons et al; Figure 5A Item 150); and a plurality

of analytical tools stored in the storage space in a stacked state (Simons et al Figure 5A Item 155), the analytical tool cartridge further comprising a retrieval mechanism for retrieving the analytical tools one at a time from the case via the retrieval port (Simons et al; Figure 5A; Item 172), the analyzer being constituted so as to install an analytical tool retrieved from the analytical tool cartridge (Figure 5A, Items 170 & 172), and to analyze a specific component in a specimen liquid supplied onto the analytical tool (Figure 5A), and the analyzer including an inserting portion into which an end portion of the analytical tool is inserted (Figure 5A) and the analytical tool cartridge and the inserting portion being provided with analytical tool fixing means for fixing the analytical tool in the analyzer (Figure 5A Item 156).

4. For Claim 18, Simons et al teaches the set of an analytical tool cartridge and an analyzer according to claim 17, wherein the analytical tool fixing means comprises a projection provided on one of the analytical tool and the inserting portion, and a recess provided in the other thereof for engaging with the projection (Column 9 lines 42-56). Examiner takes the position that the back end of the analytical tool defines a projection.

5. Claims 1-7 and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Friedlander et al (WO94/10558).

6. Regarding Claim 1, Friedlander et al teaches an analytical tool cartridge comprising: a case including a storage space (Figure 3 Item 4) and a retrieval port that communicates the storage space with an external space (Figures 4 A-C); and a plurality of analytical tools stored in the storage space in a stacked state (Figure 3); the analytical tool cartridge further comprising a retrieval mechanism for retrieving the

analytical tools one at a time from the case via the retrieval port (Page 5 1st Paragraph; manual actuator)

7. For Claim 2, Friedlander et al teaches the analytical tool cartridge according to claim 1, further comprising an opening/closing mechanism for opening and closing the retrieval port (Page 5 1st Paragraph, manual actuator).

8. For Claim 3, Friedlander et al teaches the analytical tool cartridge according to claim 2, wherein the retrieval mechanism and the opening/closing mechanism are constituted from a single operating body (Page 5 1st Paragraph), the operating body comprising: an engaging projection for integrally moving the analytical tools upon the operating body being moved in a specific direction from a standby state (Page 5 1st Paragraph), a closing portion that closes up the retrieval port in the standby state (Figure 5 Item 34); and an opening portion that opens up the retrieval port upon the operating body being moved in the specific direction from the standby state (Page 5 1st Paragraph).

9. For Claim 4, Friedlander et al teaches the analytical tool cartridge according to claim 3, wherein the case includes an annular wall portion that defines the storage space and has the retrieval port provided therein (Figure 3), the operating body being formed in a loop (Figure 5 38), disposed along an outer surface of the annular wall portion, and movable relative to the annular wall portion (Figure 5 Item 38). Examiner defines a loop a spring which is used in combination to open the close the screw cap.

10. For Claim 5, Friedlander et al teaches the analytical tool cartridge according to claim 3, wherein the analytical tools each include an engaging portion with which the

engaging projection engages (Figure 5; Items 36 & 35) Examiner takes the position that the strips have an engaging portion with which the engaging projection engages.

11. For Claim 6, Friedlander et al teaches the analytical tool cartridge according to claim 3, wherein the operating body includes an operating portion for applying a load to and thus moving the operating body (Figure 5 Item 35). Examiner takes the position that a load can be applied to the pusher.

12. For Claim 7, Friedlander et al teaches the analytical tool cartridge according to claim 1, wherein the storage space has a desiccant housed therein (Page 4 2nd Paragraph).

13. For Claim 9, Friedlander et al teaches the analytical tool cartridge according to claim 1, wherein the analytical tools are stored in the storage space in a state supported by a platform, and are supported in a state biased by the platform. (Figure 3).

14. For Claim 10, Friedlander et al teaches the analytical tool cartridge according to claim 3, wherein the case is provided with a guiding portion for guiding the operating body when the operating body is moved (Figures 4 A-C; Examiner takes the position that the guiding portions are the cartridge walls).

15. For Claim 11, Friedlander et al teaches the analytical tool cartridge according to claim 1, wherein the storage space has therein stacked on top of the analytical tools an information outputting chip from which can be outputted information relating to properties of the analytical tools (Page 4 3rd Paragraph to top of Page 5).

16. For Claim 12, Friedlander et al teaches the analytical tool cartridge according to claim 11, wherein the information outputting chip outputs information relating to a calibration curve (Page 4 3rd Paragraph to top of Page 5).

17. Claims 1-7, 9, and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Giraud (WO 02/055008). Regarding Claim 1, Giraud teaches an analytical tool cartridge comprising: a case including a storage space (Figure 5 Item 84) and a retrieval port that communicates the storage space with an external space (Figure 7 Items 80 and 120); and a plurality of analytical tools stored in the storage space in a stacked state (Figure 5 Item 80); the analytical tool cartridge further comprising a retrieval mechanism for retrieving the analytical tools one at a time from the case via the retrieval port (Figure 1 Item 1).

18. For Claim 2, Giraud teaches the analytical tool cartridge according to claim 1, further comprising an opening/closing mechanism for opening and closing the retrieval port (Figure 1 Item 18).

19. For Claim 3, Giraud teaches the analytical tool cartridge according to claim 2, wherein the retrieval mechanism and the opening/closing mechanism are constituted from a single operating body (Figure 1 Item 18), the operating body comprising: an engaging projection for integrally moving the analytical tools upon the operating body being moved in a specific direction from a standby state (Figure 1 Item 64); a closing portion that closes up the retrieval port in the standby state (Figure 7 Item 120); and an opening portion that opens up the retrieval port upon the operating body being moved in the specific direction from the standby state (Figure 7 Item 120).

20. For Claim 4, Giraud teaches the analytical tool cartridge according to claim 3, wherein the case includes an annular wall portion that defines the storage space and has the retrieval port provided therein (Figure 1 Item 12), the operating body being formed in a loop (Figure 1 Item 18), disposed along an outer surface of the annular wall portion, and movable relative to the annular wall portion (Figure 1 Item 18). Examiner defines a loop as something that is shaped like or suggestive of a loop or hook. The actuator, Item 18 has the shape of a hook.

21. For Claim 5, Giraud teaches the analytical tool cartridge according to claim 3, wherein the analytical tools each include an engaging portion with which the engaging projection engages Figure 1; Inset; test strips) Examiner takes the position that the strips have an engaging portion with which the engaging projection engages.

22. For Claim 6, Giraud teaches the analytical tool cartridge according to claim 3, wherein the operating body includes an operating portion for applying a load to and thus moving the operating body (Figure 1 Item 16).

23. For Claim 7, Giraud teaches the analytical tool cartridge according to claim 1, wherein the storage space has a desiccant housed therein (Page 5 lines 18-20).

24. For Claim 9, Giraud teaches the analytical tool cartridge according to claim 1, wherein the analytical tools are stored in the storage space in a state supported by a platform, and are supported in a state biased by the platform. (Figure 7 Item 80).

25. For Claim 10, Giraud teaches the analytical tool cartridge according to claim 3, wherein the case is provided with a guiding portion for guiding the operating body when the operating body is moved (Figure 1 Items 26, 66, 68, & 100).

Claim Rejections - 35 USC § 103

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

27. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

28. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Giraud. Regarding Claim 8, Giraud teaches the analytical tool cartridge according to claim 7, wherein the analytical tools are stored in the storage space in a state supported by a platform (Figure 1), except wherein the desiccant being fixed to the platform. Giraud does teach the use of a desiccant in the storage space (Page 5 lines 18-20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Giraud to include the desiccant to be fixed to the platform because according to Giraud, the assembly is not in use, it may be desirable to seal the strips from the environment to prevent strip degradation, something which could be brought about by humidity, among other things (Page 1 line 24 to Page 2 line 1).

29. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giraud in view of Essenpreis et al (EP1147739).

30. Regarding Claim 11, Giraud teaches the analytical tool cartridge according to claim 1, wherein the storage space has therein stacked on top of the analytical tools (Figure 1). Giraud does not teach an information outputting chip from which can be outputted information relating to properties of the analytical tools. Essenpreis et al teaches this feature (Abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Giraud with Essenpreis et al because this would allow one with diabetes to quantify or determine their blood glucose levels with a numerical value.

31. For Claim 12, Giraud in combination with Essenpreis et al teaches the analytical tool cartridge according to claim 11. Examiner takes the position that the combination of Giraud and Essenpreis et al teaches the structural limitations of the claim. (As an aside – Essenpreis et al also teaches the intended use; the information outputting chip outputs information relating to a calibration curve (Abstract)).

32. For Claim 13, Giraud in combination with Essenpreis et al teaches a set of an analytical tool cartridge and an analyzer, the set comprising: a case including a storage space and a retrieval port that communicates the storage space with an external space (Giraud; Figure 1); and a plurality of analytical tools stored in the storage space in a stacked state (Giraud; Figure 1), the analytical tool cartridge further comprising a retrieval mechanism for retrieving the analytical tools one at a time from the case via the retrieval port (Giraud; Figure 1), the analyzer being constituted so as to have installed

therein an analytical tool retrieved from the analytical tool cartridge (Essenpreis et al; Figure 1), and analyze a specific component in a specimen liquid supplied onto the analytical tool (Essenpreis et al; [0002-0003]). The combination does not teach at least one of the analytical tool cartridge and the analyzer being provided with cartridge fixing means for locating and fixing the analytical tool cartridge onto the analyzer. Essenpreis et al; Figure 7, does teach the opening of the analyzer, which defines a square notch, may define a fixing means for. It would have been an obvious matter of design choice to include a tapered notch, since applicant has not disclosed that the notches solve any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the square notch of Essenpreis et al because the square notch would be able to angle the analytical tool into the opening of the analyzer and one would get the same degree of success.

33. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giraud, Essenpreis et al, and in further view of Simons et al (US6036924).

34. Regarding Claim 14, Giraud in combination with Essenpreis et al teaches the set of an analytical tool cartridge and an analyzer according to claim 13, except wherein the cartridge fixing means includes first stopper faces and a second stopper faces for restricting movement of the analytical tool cartridge in a direction orthogonal to each of a direction of stacking of the analytical tools and a direction of insertion of the analytical tools. Simons et al teaches an alternative analyzer which would allow the analytical tool cartridge to be inserted from the bottom, the analytical tool cartridge having at least two rails on the top of the cartridge. It would have been obvious to one of ordinary skill in the

art at the time the invention was made to modify the combination of Giraud and Essenpreis et al to include stoppers because this would allow for aid in positioning the cartridge in the analyzer to make sure the cartridge is secured firmly as well as to align the analytical tools with the rest of the instrument of the analyzer (Figure 5A in Simons et al).

35. For Claim 15, Giraud in combination with Essenpreis et al and Simons et al teaches the set of an analytical tool cartridge and an analyzer according to claim 14. The combination does not teach stoppers are located on the analytical tool cartridge. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analytical tool cartridge with stoppers because this would allow for positioning the cartridge in the analyzer to make sure the cartridge is secured firmly to the analyzer using a compression fit and to align the analytical tools with the rest of the instrument of the analyzer.

36. For Claim 16, Giraud in combination with Essenpreis et al and Simons et al teaches the set of an analytical tool cartridge and an analyzer according to claim 15. Giraud teaches the cartridge fixing means is constituted from notches provided in the case (Figure 7A). Simons et al further teaches recessed portions provided in the analyzer (Figure 5A Item 170).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BOBBY RAMDHANIE whose telephone number is (571)270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

Art Unit: 1797

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bobby Ramdhanie, Ph.D./
Examiner, Art Unit 1797
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/Walter D. Griffin/
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